IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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| Application No. | : | 10/564,674 | Confirmation No. | : | 1707 |
| Applicants | : | MARCEL WIJLAARS ET AL. | | | |
| Filed | : | July 14, 2006 | | | |
| Title | : | TISSUE SUBSTITUTE MATERIAL | | | |
| Group Art Unit | : | 1707 | | | |
| Examiner | : | Caralynne E. Helm | | | |
| Customer No. | : | 28289 | | | |

Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

**PRE-APPEAL BRIEF REQUEST FOR REVIEW**

Sir:

For the reasons set forth herein, Applicants respectfully submit that the final Office Action is based upon improper rejections of the claims and does not establish the asserted *prima facie* case of obviousness based on the cited references.

I hereby certify that this correspondence is being electronically submitted to the United States Patent and Trademark Office on June 29, 2010

Florence P. Trevethan
(Name of Person Submitting Paper)

Florence P. Trevethan 6/29/1010
Signature Date

**Rejections of claims 8-9 and 12-14 under 35 U.S.C §103(a) over Malmonge, Slivka, Pissis and Young and Rejections of claims 8 and 10-11 under 35 U.S.C §103(a) over Malmonge, Slivka, Pissis, Young and Kou**

Claims 8-9 and 12-14 are rejected under 35 U.S.C. §103(a) as being unpatentable over Malmonge et al. in view of Slivka et al. (Tissue Engineering 2001 7:767-780), Pissis et al. and Young et al. Additionally claims 8 and 10-11 are rejected under 35 U.S.C. §103(a) as being unpatentable over Malmonge in view of Slivka, Pissis and Young as applied to claims 8-9 and 12-14 above, and further in view of Kou (previously cited).

Claim 8 is directed to a material for cartilage-like material substitution, comprising a fibre-reinforced polymerized hydrogel. The polymerized hydrogel contains 10-70% (m/m) swellable fibres (based on the dry matter) and the length of the fibres is at least a millimeter. Additionally, 1-5% (m/m) (based on the dry matter) of a substance that contains ionized groups has been added to said polymerized hydrogel and the swellable fibres have sucked up at least one monomer solution prior to polymerization of the hydrogel.

When making a rejection under 35 U.S.C. §103, the Examiner has the burden of establishing a *prima facie* case of obviousness and must establish some reason to combine the references. *KSR Int'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 131 (2007); *Takeda Chemical Industries, Ltd. v. Alpharpharm Pty., Ltd.*, 492 F.3d 1350, 1356-1357 (Fed. Cir. 2007).

A combination of known elements will not yield predictable results if the references teach away from the claimed invention. *Takeda Chemical*, 492 F.3d at 1359; *Ortho-McNeil Pharmaceutical, Inc. v. Mylan*, 520 F.3d 1358, 1364 (Fed. Cir. 2008); and *Ex parte Ikeda*, App. No. 08/352,079, Appeal 2008-0492, Slip Op. at 7 (BPAI Mar. 26, 2008). For example, in *Takeda Chemical*, the post-*KSR* Federal Circuit noted that the recited compound, which was a modified version of compound b, was not recognized at the pertinent time as a suitable candidate for treatment of Type II diabetes. 492 F.3d at 1359. *Takeda Chemical* involved United States Patent No. 4,687,777, which was directed to a compound for the treatment of Type II diabetes. *Id.* at 1352-1354. The defendant argued that the patent was obvious in view of a reference that disclosed compound b, because the claimed compound could be synthesized from compound b by routine means. *Id.* at 1357. However, the Federal Circuit affirmed that the patent was not obvious because the prior art taught away from choosing compound b as a starting point. *Id.* at 1359-1361. Compound b was known to have unwanted side effects, and there was nothing in the prior art to suggest that homologation would decrease the unwanted side effects. *Id.* at 1359-1360.

In a more recent case, the Board reversed an Examiner's rejection for failing to provide the requisite reason to combine the references. *Ikeda*, App No. 08/352,079 at 7. The *Ikeda* application was directed to a method of removing hydrocarbons from exhaust gases. *Id.* at 2. In pertinent part, the claims recited an absorption catalyst B located downstream of a catalyst A in the direction of the exhaust gas. The claims were rejected as unpatentable under 35 U.S.C. §103 in view of Swaroop, Abe and Patil. *Id.* at 3. Swaroop taught positioning the absorption catalyst B upstream of catalyst A. *Id.* at 5. To remedy the deficiency in the art, the Examiner cited "Patil and Abe as evidence of the 'conventionality of positioning the adsorbent catalyst 1 either upstream or downstream of a [three-way] catalyst 3' and thus conclude[d] that it would have been obvious to one of ordinary skill in this art to select an appropriate location for the adsorbent catalyst 16 in the apparatus of Swaroop ...." *Id.* at 5-6. The Board held that:

> The Examiner has failed to provide any cogent reason or technical discussion to support the conclusion that one of ordinary skill in this art would have employed the relative positions of the catalysts in Abe and Patil without the use of the other teachings of these references, namely an auxiliary heater and bypass lines with valving. Second, the Examiner has not explained why one of ordinary skill in this art would have used the teachings of Patil, requiring bypass lines and valving, when Swaroop specifically ***teaches away*** from the use of valving and bypass lines [*citation omitted*]. Third, the Examiner has not supplied convincing reasoning or technical discussion to support the proposed switch in relative position of the catalysts when Swaroop specifically teaches that the exhaust gas is "modified" by the adsorbent catalyst and this modified form of the exhaust gas is *then* sent to the main or three-way catalyst to undergo conversion to innocuous products [*citation omitted*]. ... Fourth, the Examiner has not explained why one of ordinary skill in this art would have ***proceeded contrary to the teachings of Patil***, namely the teachings that "it is not possible merely to place zeolite 'in-line' in the exhaust system when the [main] catalyst has reached an effective temperature and unconverted hydrocarbons would still be discharged to the atmosphere" [*citation omitted*].

Emphasis added, *Ikeda*, App. No. 08/352,079 at 7.

Following the reasoning stated in *Takeda Chemical*, the Office Action must provide some explanation why one of ordinary skill in the art would use 10-70% (m/m) swellable fibres (based on the dry matter) that are at least a millimeter long in the claimed cartilage-like material substitution.

Like *Takeda Chemical*, one of ordinary skill in the art would have had no reason to use 10-70% (m/m) swellable fibres (based on the dry matter) that are at least a millimeter long in the claimed cartilage-like material substitution. Particularly, Pissis is cited in combination with Malmonge, Slivka, and Young and is applied to teach the incorporation of Nylon particles (fibres).

Pissis is concerned solely with the dielectric and water sorption properties of poly(hydroxyethyl acrylate) (pHEA) gel reinforced with Nylon nanoparticles. (See Title and first sentence of Introduction). [Huyghe Declaration, paragraph 6]. Nowhere in Pissis is reference made to use 10-70% (m/m) swellable fibres (based on the dry matter) that are at least a millimeter long in the claimed cartilage-like material substitution (i.e., > than 10% of swellable fibres). [Huyghe Declaration, paragraph 9]. Additionally, the maximum weight percentage of nanoparticles in the hydrogel that could be obtained by Pissis was 10% before undesired agglomeration occurs resulting in a gel-like paste which makes the hydrogel unsuitable for mixing with a monomer mixture. (Pissis, page 561, final sentence) Therefore, Applicants assert that Pisses teaches away from using 10-70% (m/m) swellable fibres (based on the dry matter) that are at least a millimeter long in the claimed cartilage-like material substitution.

Additionally, Young is applied to teach a fibre reinforced polyHEMA as a biomaterial. Applicants assert that the smooth artificial skin substitute materials according to Young is characterized by being ultrathing (<0.23MM) and containing a <1.66% of fibres. Therefore, Young provides no motivation to use 10-70% (m/m) swellable fibres (based on the dry matter) that are at least a millimeter long in the claimed cartilage-like material substitution

Additionally, one of ordinary skill in the art would not be motivated to combine Malmonge in view of Slivka, Pissis and Young or Malmonge in view of Slivka, Pissis and Young, and further in view of Kou, since Pissis teaches away from using 10-70% (m/m) swellable fibres (based on the dry matter) that are at least a millimeter long in the claimed cartilage-like material substitution.

Therefore, Malmonge in view of Slivka, Pissis and Young or Malmonge in view of Slivka, Pissis and Young and further in view of Kou would not render the claimed cartilage-like material obvious. For the foregoing reasons, withdrawal of the rejection and reconsideration of claims 8-14 ise respectfully requested.

## Conclusion

Applicants respectfully request reconsideration and submit that all claims are in condition for allowance. Early notification of a favorable consideration is respectfully requested. In the event any issues remain, Applicants would appreciate the courtesy of a telephone call to their counsel at the number listed below to resolve such issues and place all claims in condition for allowance.

Respectfully submitted,

THE WEBB LAW FIRM

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